PERIMETER® Interbody Fusion Device
510(k) Summary
February 2009

I. **Company:** **Medtronic Sofamor Danek**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

SEP 2 9 2009

Contact: **Lee Grant**
Principal, Regulatory Affairs

II. **Proprietary Trade Name: PERIMETER® Interbody Fusion Device**

III. **Classification Name:** Intervertebral Body Fusion Device (21 CFR 888.3080)

IV. **Product Code: MAX**

V. **Product Description**

The PERIMETER® Interbody Fusion Device consists of cages which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft. The PERIMETER® Interbody Device is to be used with supplemental instrumentation.

This device is offered in both titanium alloy and PEEK (POLYETHERETHERKETONE) versions. This interbody device is provided in both sterile and non-sterile forms. Refer to the package label for sterility information.

The subject PERIMETER® Interbody Fusion Device is offered in a variety of sizes ranging from 8mm to 20mm in height and between 19mm and 28mm in width. The device is designed with teeth across both superior and inferior surfaces to allow the implant to grip the superior and inferior end plates, thus providing expulsion resistance.

V. **Indications**

The PERIMETER® Interbody Fusion Device is indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative

treatment. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior, lateral and oblique. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

VI. Substantial Equivalence

Documentation, including mechanical test results and published literature, was provided which demonstrated that the subject PERIMETER® Interbody Fusion Device is substantially equivalent to several recently down classified interbody cages including, the CLYDESDALE® Spinal System (K083026, SE 12/29/08); the LT-CAGE® Peek Lumbar Tapered Fusion Device (P970015, Medtronic Sofamor Danek, Approved 9/10/03); the BAK® Cage (P950002, Zimmer Spine, Approved 7/8/03); the RAY® Threaded Fusion Cage (P950019, Stryker, Approved 9/4/03); the Lumbar I/F Cage (DePuy, P960025); as well as to the CAPSTONE® Spinal System K073291 (SE 04/24/08) and the VERTE-STACK® Spinal System (K041452, SE 06/24/04).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek
% Mr. Lee Grant
Principal, Regulatory Affairs
1800 Pyramid Place
Memphis, Tennessee 38132

SEP 2 9 2009

Re: K090353
Trade Name: PERIMETER® Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: II
Product Code: MAX
Dated: September 21, 2009
Received: September 22, 2009

Dear Mr. Grant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K090353

Device Name: PERIMETER® Interbody Fusion Device

Indications for Use:

The PERIMETER® Interbody Fusion Device is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior, lateral and oblique. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090353